

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,603	08/01/2003	Lionel Vedrine	P-4604P1C1	4329
26253 7	590 09/08/2004	EXAMINER		
	IIGHET, VP AND C	MITCHELL, 1	MITCHELL, TEENA KAY	
BECTON, DICKINSON AND COMPANY			ART UNIT	PAPER NUMBER
1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880		3743		

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

				. ^			
7		Application No.	Applicant(s)	1/1/			
		10/632,603	VEDRINE ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Teena Mitchell	3743				
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence ad	ldress			
THE - Exterest after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL' MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period v re to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered time the mailing date of this c D (35 U.S.C. § 133).	ly. ommunication.			
Status							
1)⊠	Responsive to communication(s) filed on <u>01 A</u>	<u>ugust 2003</u> .					
2a) <u></u> □	This action is FINAL . 2b)⊠ This	action is non-final.					
3) 🗌	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposit	ion of Claims						
4) 🖾	☑ Claim(s) <u>1-76</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)⊠	Claim(s) <u>1-13,15-21,23-66 and 73-76</u> is/are rejected.						
•	Claim(s) <u>14,22,67-72</u> is/are objected to.						
8)	Claim(s) are subject to restriction and/o	r election requirement.					
Applicat	ion Papers						
9)⊠	The specification is objected to by the Examine	er.					
10)⊠ The drawing(s) filed on <u>01 August 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)[The oath or declaration is objected to by the Ex	kaminer. Note the attached Office	Action or form P	TO-152.			
Priority (under 35 U.S.C. § 119						
-	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document	s have been received.					
	3. Copies of the certified copies of the prior			Stage			
	application from the International Burea		od III tillo i vational	Glago			
* (See the attached detailed Office action for a list		ed.				
Attachmer	•	, 	(DTO 440)				
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D					
3) 🔲 Infor	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date			O-152)			

Art Unit: 3743

DETAILED ACTION

Priority

While applicant in the first paragraph of the disclosure list that the instant application is a Continuation of application 09/829,843, the current status of the 09/829,843 application is missing, also a listing of the other related applications (e.g., 09/417,346; 09/993,098).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. While the examiner has reviewed all patents listed in parent applications related to the instant application, however, if applicant desires the information to be printed on any patent that may issue from the instant application applicant must submit an appropriate 1449, listing such references. (MPEP 609).

Specification

The abstract of the disclosure is objected to because it is longer than 150 words (CFR 1.72). Correction is required. See MPEP § 608.01(b).

Art Unit: 3743

Claim Objections

Claim 76 is objected to because of the following informalities: Claim 76 is dependent from claim 1 which is an apparatus claim. The examiner believes applicant intended claim 76 to depend from claim 61, therefore line 1 of claim 76 should be amended to read —in claim 61—. Correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13, 15-21, 23-44, and 50-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,622,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 1 of the instant application limitations can be found in claim 1 of the patent. Claim 1 of the instant application does not include all the elements of claim 1 of the patent. Therefore, the patented claim 1 "anticipates" the application claim 1 (In re Goodman, 11 F.3d 1046, 29 USPQ 2010 (Fed. Cir. 1993). With respect to claim 2, of the instant application,

Art Unit: 3743

the limitations can be found in claim 7 of the patent. With respect to claim 3 of the instant application, the limitations can be found in claim 8 of the patent. With respect to claim 4 of the instant application, the limitations can be found in claim 9 of the patent. With respect to claim 5 of the instant application, the limitations can be found in claim 10 of the patent. With respect to claim 6 of the instant application, the limitations can be found in claim 11 of the patent. With respect to claim 7 of the instant application, the limitations can be found in claim 12 of the patent. With respect to claim 8 of the instant application, the limitations can be found in claim 13 of the patent. With respect to claim 9 of the instant application, the limitations can be found in claim 14 of the patent. With respect to claim 10 of the instant application, the limitations can be found in claim 15 of the patent. With respect to claim 11 of the instant application, the limitations can be found in claim 16 of the patent. With respect to claim 12 of the instant application, the limitations can be found in claim 2 of the patent. With respect to claim 13 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 15 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 16 of the instant application, the limitations can be found in claim 2 of the patent. With respect to claim 17 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 18 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 19 of the instant application, the limitations can be found in claim 3 of the patent. With respect to claim 20 of the instant application, the limitations can be found in claim 4 of the

Art Unit: 3743

patent. With respect to claim 21 of the instant application, the limitations can be found in claim 5 of the patent. With respect to claim 23 of the instant application, the limitations can be found in claim 6 of the patent. With respect to claim 24 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 25 of the instant application, the limitations can be found in claim 2 of the patent. With respect to claim 26 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 27 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 28 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 29 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 30 of the instant application, the limitations can be found in claim 3 of the patent. With respect to claim 31 of the instant application, the limitations can be found in claim 4 of the patent. With respect to claim 32 of the instant application, the limitations can be found in claim 5 of the patent. With respect to claim 33 of the instant application, the limitations can be found in claim 6 of the patent. With respect to claim 34 of the instant application, the limitations can be found in claim 7 of the patent. With respect to claim 35 of the instant application, the limitations can be found in claim 8 of the patent. With respect to claim 36 of the instant application, the limitations can be found in claim 9 of the patent. With respect to claim 37 of the instant application, the limitations can be found in claim 10 of the patent. With respect to claim 38 of the instant application, the limitations can be found in claim 11 of the patent. With respect to claim 39 of the instant application,

Art Unit: 3743

the limitations can be found in claim 12 of the patent. With respect to claim 40 of the instant application, the limitations can be found in claim 13 of the patent. With respect to claim 41 of the instant application, the limitations can be found in claim 14 of the patent. With respect to claim 42 of the instant application, the limitations can be found in claim 15 of the patent. With respect to claim 43 of the instant application, the limitations can be found in claim 16 of the patent. With respect to claim 44 of the instant application, the limitations can be found in claims 1, 2, and 10 of the patent. It would have been obvious to one of ordinary skill in the art at the time the invention was made that in the instant application claim the limitations of "preselected axial distance corresponding to half the distance that said stopper is capable of moving within said barrel to administer about half of the substance contained by said syringe barrel" based on the patent claim 1 "a portion of the substance corresponding to a dosage of the substance" inasmuch as a portion of the substance is delivered it would be obvious to one of ordinary skill in the art that that a portion which constitutes a dose could be half the substance in the barrel. With respect to claim 50 of the instant application, the limitations can be found in claim 6 of the patent. With respect to claim 51 of the instant application, the limitations can be found in claim 7 of the patent. With respect to claim 52 of the instant application, the limitations can be found in claim 1 of the patent. With respect to claim 53 of the instant application, the limitations can be found in claim 9 of the patent. With respect to claim 54 of the instant application, the limitations can be found in claim 10 of the patent. With respect to claim 55 of the instant application, the limitations can be found in claim 11

Art Unit: 3743

of the patent. With respect to claim 56 of the instant application, the limitations can be found in claim 12 of the patent. With respect to claim 57 of the instant application, the limitations can be found in claim 13 of the patent. With respect to claim 58 of the instant application, the limitations can be found in claim 14 of the patent. With respect to claim 59 of the instant application, the limitations can be found in claim 15 of the patent. With respect to claim 60 of the instant application, the limitations can be found in claim 15 of the patent. With respect to claim 60 of the instant application,

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-24 of U.S. Patent No. 6,382,204. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 44 of the instant application limitations can be found in claim 19 of the patent. However the patented claim is more specific than the instant application claim 44. Therefore, the patented claim 19

Art Unit: 3743

"anticipates" the application claim 44. In re Goodman, 11 F.3d 1046, 29 USPQ 2010 (Fed. Cir. 1993). With respect to claim 45 of the instant application, the limitations can be found in claim 20 of the patent. With respect to claim 46 of the instant application, the limitations can be found in claim 19 of the patent. With respect to claim 47 of the instant application, the limitations can be found in claim 21 of the patent. With respect to claim 48 of the instant application, the limitations can be found in claim 22 of the patent. With respect to claim 49 of the instant application, the limitations can be found in claim 23 of the patent. With respect to claim 50 of the instant application, the limitations can be found in claim 24 of the patent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 61-66 and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,530,371. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 61 of the instant

Art Unit: 3743

application, limitations can be found in claim 1 of the patent, except the patented claim uses the language "first nostril" and "second nostril". One of ordinary skill in the art at the time the invention was made would know that in claim 61 the use of "said nostril" and "into said other nostril" would constitute the first and second nostril of a user. With respect to claim 62 of the instant application, the limitations can be found in claim 2 of the patent. With respect to claim 63 of the instant application, the limitations can be found in claim 3 of the patent. With respect to claim 64 of the instant application, the limitations can be found in claim 4 of the patent. With respect to claim 65 of the instant application, the limitations can be found in claim 5 of the patent. With respect to claim 66 of the instant application, the limitations can be found in claim 6 of the patent. With respect to claims 73-76 of the instant application, one of ordinary skill in the art at the time the invention was made would have found in obvious to select any of the claimed substances claimed based on the needs of the individual user and the type of treatment required because all listed substances are well known in the respiratory art for delivery via the nasal area.

Allowable Subject Matter

Claims 14, 22, and 67-72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (703) 308Application/Control Number: 10/632,603 Page 10

Art Unit: 3743

4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeur hald Teena Mitchell Examiner Art Unit 3743 September 4, 2004